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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,347	07/14/2005	Ali Rezai	12637/58	6087
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KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005			EXAMINER FLORY, CHRISTOPHER A	
			ART UNIT 3762	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/502,347

Applicant(s)

REZAI ET AL.

Examiner

Christopher A. Flory

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16,18,19,21-25 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16,18,19,21-25 and 27-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5 and 7-31 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kieval (US 6,178,349, hereinafter Kieval'349). It is noted that Testerman et al. (US 5,344,438, hereinafter Testerman'438) is incorporated by reference (col. 5, lines 52-55) and also relied upon in this rejection. Citations to Kieval'349 will be made in plain text, while citations to Testerman'438 will be made in ***bold italic text***.

Regarding claims 1, 13, 14, 17- 20, 22, 23, 25 and 26, Kieval'349 discloses a delivery device (Kieval'349: Fig. 1) for stimulating a ganglion of the sympathetic nervous system (Kieval'349: Fig. 2; column 4, lines 14-45) comprising a first and second series of flexibly connected delivery contacts (Kieval'349: Fig. 1, first series comprises electrode and reservoir system 92, second series system 94; column 5, lines 40-45.

Testerman'438: Fig. 3, any of delivery contacts 64-86 can be set up in series (col. 3, lines 35-57)). Regarding Kieval'349, it is noted that the electrode 116 and reservoir 114 of Fig. 2 are both delivery ports, and that the leading contact (114) is engagably associated with the trailing delivery contact (116) in an operative position (column 6, lines 22-24 and 54-63; column 7, lines 31-34). Regarding Testerman'438, it is noted

Art Unit: 3762

that any of **contacts 62-86 in Fig. 3** can be considered the leading and trailing contacts, all of which are engagably associated in both the first and second series.

Regarding claims 1, 14, 19 and 23 it is noted that the terms "delivery contacts," "probe," "terminal member" and "clamping members" all substantially define the same or substantially similar structures, each of which is clearly anticipated by Kieval'349.

Regarding claims 2, 3 and 11, the electrode/reservoir configuration of Kieval'349 can be considered concave or convex depending on whether you refer to the inside or outside portion of the cuff. Alternatively, it can be seen that the electrode plate on the inside of the cuff is concave, whereas the electrode material that extends around the flat edges of the cuff (Fig. 2 under reference 116) holds a generally convex shape. Additionally, the multi-electrode embodiments, such as the one illustrated by Testerman'438 also show a first series (**Fig. 3, electrodes 62-66**) arranged in a concave configuration relative to the centerline, and a second series (**Fig. 3, electrodes 72-76**) in a convex configuration relative to the centerline.

Regarding claim 4, Testerman'438 discloses a third series between and connected to both the first and second series (**Fig. 3, contacts 82-86; column 3, lines 35-57**).

Regarding claims 7 and 8, Kieval'349 discloses that the delivery contacts can be either electrodes or drug ports (ABSTRACT).

Regarding claim 9, and further regarding claim 14, the device disclosed in Kieval'349 is capable of being inserted into a ganglion.

Regarding claim 10, Kieval'349 discloses delivery contacts having a trapezoidal configuration (Figs. 3 and 4, wherein the electrode and reservoir are each trapezoidal). Alternatively, Testerman'438 discloses trapezoidal contacts (**column 2, lines 39-45**).

Regarding claim 12, and further regarding claims 14, 19 and 23, Kieval'349 discloses an axially elongated shaft (Fig. 1, leads 96 & 98). The shaft is considered slidably engagable with the device because the suture means (Fig. 2, left of reference 94) is slidable along the lead to secure the cuff. Additionally, the cuff is slidable or positionable along the nerve.

Regarding claims 15, 21 and 24, the suture element shown in Figure 2 of Kieval'349 (**element 140 of Testerman'438**) is considered to be a detachable limit stop.

Regarding claim 27, Kieval'349 discloses clamping members hingedly connected to each other. The nerve cuff 112 shown in Fig. 2 is disclosed as being flexibly deformable, wherein the flat front edges are temporarily drawn apart and placed around the nerve, wherein upon release of tension the cuff returns to its original conformation and holds the cuff substantially in contact with the nerve without need for sutures. Therefore, if one considers the front flat edges to be the clamping members, they are hingedly connected due to the flexible nature and intended application of the nerve cuff. Alternatively, each nerve cuff 92 and 94 shown in Figure 1 can be considered a clamping member, those hingedly connected by element 100.

Regarding claim 16, the first and second probes disclosed in Kieval'349 are each considered to define a first and second prong for the same reasoning provided regarding claim 27.

Regarding claims 28-31, Kieval'349 discloses a method of stimulating a ganglion comprising encasing a delivery device around a portion of a sympathetic ganglion and providing a stimulation signal to the ganglion while maintaining an ovoid shape (column 4, lines 14-45; column 5, lines 2-26), wherein a semi-circular cuff is considered to be substantially ovoid.

Further regarding claims 30 and 31, it is noted that the stimulator and shaft are considered slidably engagable for the reasons set forth above in regards to claim 12

Claim Rejections - 35 USC § 102/103

3. Claim 5 stands rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kieval'349.

Regarding claim 5, Kieval'349 discloses the first, second and third series each comprising four delivery contacts, wherein one can consider the reservoir to be a first contact, and the three series electrodes (shown as the disclosed embodiment of ***Testerman'438, Fig. 3***) as the remaining three electrodes to make a total of four contacts. Alternatively, Kieval'349 discloses the use of a plurality of electrodes (column 5, lines 40-45), but does not expressly disclose 4 electrodes. It would have been obvious to one having ordinary skill in the art at the time of the invention to include 4 contacts, since it has been held that mere duplication of essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 6 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Kieval'349.

Regarding claim 6, Kieval'349 discloses a first, second and third series of contacts each having a respective diameter, but does not expressly disclose that the third diameter is greater than the first or second diameters. It would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the invention to modify the system as taught by Kieval'349 with the larger third diameter, because Applicant has not disclosed that a third diameter larger than either of the first or second diameter provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the nerve cuff as taught by Kieval'349, because it provides a means for securing the nerve cuff around a nerve in electrical contact therewith, and since it appears to be an arbitrary design consideration which fails to patentably distinguish the instant application over Kieval'349.

Therefore, it would have been an obvious matter of design choice to modify the system of Kieval'349 to obtain the invention as specified in the claim(s).

Response to Arguments

6. Applicant's arguments, see paragraph 2 of page 8, filed 2 August 2007, with respect to the objection to claims 17, 20 and 26 have been fully considered and are persuasive. In light of the cancellation of these claims, the objection to claims 17, 20 and 26 has been withdrawn.

7. Applicant's arguments filed 2 August 2007 have been fully considered but they are not persuasive. Claims 1-5 and 7-31 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kieval'349.

8. Regarding Applicant's statement to the propriety of relying on Testerman'438 (page 8, paragraph 3), it is noted that incorporation by reference is a matter of necessity rather than convenience, wherein there is no more practical or concise way to define the invention than to substantially duplicate a drawing, table, or text from the referenced document (Ex parte Fressola, 27 USPQ2d 1608, 1609 (BPAI 1993)). Therefore, such an incorporation by reference is considered to make the cited document (in this case Testerman'438) a critical and inseparable part of the disclosure of the Kieval'349 reference, and therefore the rejection under §102(b) as made was proper.

9. Regarding claims 1-5 and 7-13, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the respective series forming a secure elliptical or circular configuration) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed.

Art Unit: 3762

Cir. 1993). While defining a secure elliptical or circular configuration is appreciably one potential definition of "engagably associated," it is certainly not a limiting one. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). One skilled in the art would not reasonably assume "engagably associated" to mean exclusively circular in nature, but rather could apply a wide range of interpretations such as electrically connected or functional together to be able to engage or clasp a body structure. Even if it were sufficiently defined that engagably associated meant strictly forming a secure elliptical or circular configuration, it is noted that the flexible nature of the Kieval'349 substrate would make the Kieval'349 device capable of bending such that the leading and trailing contacts could be made to touch in such a configuration.

10. Regarding claims 14-18, in response to applicant's argument that neither Kieval'349 or Testerman'438 teach a prove "insertable in a ganglion" but rather teach devices for use as a cuff around a nerve, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Herein, both Kieval'349 and Testerman'438 meet the structural requirements of the claims, and further would be capable of use in relation to a ganglion, and inserted therein.

11. Regarding applicant's argument as it applies to claims 19-27 that Kieval'349 fails to teach a slidably engagable electrode body, it is noted that the rejection as made

provides support for this limitation. The suture structure of the electrode body is disclosed as slidable along the lead, and furthermore the cuff is slidable along a nerve.

12. Regarding applicant's argument as it applies to both claims 19-22 and 28-31 that Kieval'349 is not "adjacently positionable to a ganglion, it is noted that this is an inherent limitation of any nerve cuff structure as ganglia are specialized nerve structures that are found along the nerve chain, and therefore location on a nerve is inherently adjacent a ganglion. Furthermore, Kieval'349 explicitly states in the cited sections (column 5, lines 11-13) that the stimulating device is placed at the right or left stellate ganglion in one preferred embodiment.

13. In response to applicant's argument that Kieval'349 is designed for use with nerves rather than ganglia, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, Kieval349 meets the structural claim limitations and further is capable of use with ganglia as well as nerves. It is further noted that a ganglion is merely a specialized nerve structure comprising a group of nerve cells, and one could therefore reasonably interpret the disclosure of use with nerves in Kieval'349 as extending additionally to the specialized ganglion structure, which is itself merely a collection of nerves.

Alternatively, Kieval'349 explicitly states that it can be used in conjunction with a ganglion in column 5, lines 11-13.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

29 August 2007

/George Manuel/
Primary Examiner